K073623

MAR 13 2008

510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

Atlantis™ 018 Peripheral Imaging Catheter

Submitted By Boston Scientific Corporation
47900 Bayside Parkway
Fremont, CA 94538

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Date Prepared December 21, 2007

Proprietary Name Atlantis™ 018 Peripheral Imaging Catheter

Common Name(s) Ultrasonic Diagnostic Imaging Catheter
Ultrasonic Diagnostic Transducers (ITX)
Intravascular Ultrasound Catheter (OBJ)

Classification Name(s) 21 CFR Part 892. 1570 (ITX, OBJ)
Diagnostic Ultrasonic Transducer

Predicate Devices

The Atlantis™ 018 Peripheral Imaging Catheter is substantially equivalent to the following devices:

Product	510(k)	Clearance Date
Atlantis™ SR Pro Coronary Imaging Catheter	K063312	November 30, 2006
Sonicath Ultra™ Imaging Catheter (3.2F)	K060947	April 19, 2006

Description of the Device

The Atlantis™ 018 Peripheral Imaging Catheter is a sterile, single patient use 40MHz transducer imaging catheter, intended for intravascular ultrasound examination of peripheral vessels. This imaging catheter is designed to be operated with Boston Scientific Corporation (BSC) Intravascular Ultrasound (IVUS) Systems; iLab™ (K072517), Galaxy2/Galaxy (K980851), and Clearview™ Ultra (K921750).

The Atlantis™ 018 Peripheral Imaging Catheter consists of two main assemblies:

- Imaging core
- Catheter body

The catheter body comprises three sections:

- Distal lumen
- Proximal single lumen
- Telescoping section

The distal lumen and proximal single lumen sections compose the "working length" of the catheter, and the telescoping section remains outside of the guiding catheter and/or introducer sheath. The telescoping shaft section allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement

of the transducer occurs from the proximal end of the wire exit port to the proximal end of the distal lumen.

The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking 40 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end makes the connection to the BSC IVUS System Motor Drive Unit (MDU).

Intended Use / Indications for Use

The Atlantis™ 018 Peripheral Imaging Catheter is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Device Technology Characteristics and Comparison to Predicate Device

The Atlantis™ 018 Peripheral Imaging Catheter and the predicate devices are comprised of a catheter body and an imaging core. The Atlantis™ 018 Peripheral Imaging Catheter is equivalent in terms of design, operational characteristics, and material composition to the Atlantis™ SR Pro Coronary Imaging Catheter.

In terms of intended use and operational characteristics, the Atlantis™ 018 Peripheral Imaging Catheter is equivalent to the Sonicath Ultra™ 3.2F Peripheral Imaging Catheter. The use of the device in intravascular ultrasound imaging is the same among the 2 predicate devices and Atlantis™ 018; however both Atlantis™ 018 and Sonicath Ultra™ 3.2F are indicated for peripheral use, while Atlantis™ SR Pro is indicated for coronary use.

Non-Clinical Test Results

The performance test results of the Atlantis™ 018 Peripheral Imaging Catheter demonstrate the device meets or exceeds the performance requirements for the specified intended use. Bench, acoustic output, animal, and biocompatibility tests were conducted on the device.

Bench Testing

Bench testing was conducted to evaluate the physical integrity and functionality of the catheter sheath and imaging core. The testing consisted of dimensional and functional verification. The Atlantis™ 018 Peripheral Imaging Catheter met or exceeded all required specifications.

Acoustic Output

Acoustic output testing was conducted as specified in the FDA guidance document *Information for Manufacturers Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers*, issued in 1997. The Atlantis™ 018 Peripheral Imaging Catheter test results are below the FDA Track 1 specified limits.

Animal Testing

The Atlantis™ 018 Peripheral Imaging Catheter was evaluated through animal testing to assess the in-vivo deliverability and imaging characteristics of the catheter. The device performance demonstrated clinical acceptability for the intended use.

Biocompatibility Testing

Biocompatibility tests were selected in accordance with *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, dated May 1, 1995. The biocompatibility test results demonstrate the device is acceptable for its intended use.

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Conclusion

The Atlantis™ 018 Peripheral Imaging Catheter is substantially equivalent to the Atlantis™ SR Pro Coronary Imaging Catheter and the Sonicath Ultra™ 3.2F Peripheral Imaging Catheter. The Atlantis™ 018 Peripheral Imaging Catheter test results support the determination of substantial equivalence to predicate devices, and confirm the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Boston Scientific Corporation
c/o Ms. Emilly Tojima
Regulatory Affairs Specialist II
47900 Bayside Parkway
Fremont, CA 94538

Re: K073623
Trade Name: Atlantis 018 Peripheral Imaging Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Codes: ITX, OBJ
Date: December 21, 2007
Received: December 26, 2007

Dear Ms. Tojima:

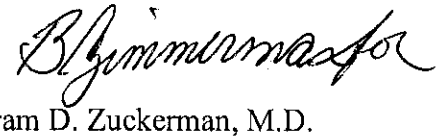
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2.0 Indications for Use

510(k) Number: K073623

Device Name: Atlantis™ 018 Peripheral Imaging Catheter

Indications for Use:

The Atlantis™ 018 Peripheral Imaging Catheter is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073623